Department of Health and Human Services
Maine Center for Disease Control and Prevention

Protocol for seasonal influenza vaccine administration for school-based immunization clinics --2009-2010

Definition: Influenza is an acute infectious disease characterized by fever, chills, myalgia, headache, respiratory and/or gastrointestinal symptoms. Influenza A and B are two types of influenza viruses that cause human disease. Influenza viruses are spread from person to person primarily through the coughing and sneezing of infected persons. The typical incubation period for influenza is 1-4 days with and average of 2 days.

Purpose: The purpose of this protocol is to provide guidance to health care providers on the administration of seasonal influenza vaccine at school-based clinics in Maine during the 2009-2010 influenza season.

Procedure:

1. The health care provider shall be authorized to administer the influenza vaccine at school-based clinics.

   An emergency plan must be in place in the event of anaphylaxis or symptoms of immediate hypersensitivity following administration of the vaccine. Prior to the clinic, all health care providers attending the clinic shall be familiar with the emergency procedures for anaphylaxis and the administration of epinephrine and diphenhydramine (Benadryl).

   In the advent of an occupational blood borne exposure, refer to MMWR, June 29, 2001, Volume. 50, RR-11;1:42. (www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm)

2. Prior to the administration of the vaccine the individual/parent/guardian shall be given the Vaccine Information Statement (VIS).

3. The individual/parent/guardian shall be notified that they are expected to remain for 15 minutes at the clinic site after receiving the vaccine for the purpose of observing for a reaction to the vaccine.

4. By use of the consent form, the health care provider shall obtain a health history for the purpose of determining possible contraindications to receiving the vaccine.

5. The following persons are not to receive the injectable influenza vaccine:

   A. Children less than 6 months of age

   B. Persons who are known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine.

C. Persons that have had a severe allergic reaction after receiving a previous dose of influenza vaccine

D. Persons with a history of Guillian-Barre Syndrome.

E. Persons who are moderately or severely ill

6. The following persons are not to receive the intranasal vaccine:

A. Persons 50 years of age or older or children less than 2 years of age.

B. Children younger than 5 with asthma or one or more episodes of wheezing within the past year.

C. People who have long-term health problems with heart disease, lung disease, asthma, kidney or liver disease, metabolic disease such as diabetes, and anemia or other blood disorders

D. Anyone with certain muscle or nerve disorders such as seizure disorders or cerebral palsy that can lead to breathing or swallowing problems.

E. Anyone with a weakened immune system.

F. Children or adolescents on long-term aspirin treatment.

G. Pregnant women.

H. Persons in close contact with anyone who has a severely weakened immune system requiring care in a protected environment, such as bone marrow transplant unit.

I. Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose.

J. Persons who are known to have anaphylactic hypersensitivity to eggs or to other components of the influenza vaccine.

K. Persons that have had a severe allergic reaction after receiving a previous dose of influenza vaccine

L. Persons with a history of Guillian-Barre Syndrome.

M. Persons who are moderately or severely ill

7. Persons with a negative health history (no contraindications) or who have written permission from their primary health care provider may receive the vaccine.

8. The health care provider shall have the individual/parent/guardian sign the appropriate consent form which shall include the following.

    a. The vaccine recipient's name, address, telephone number, age, and name of their primary healthcare provider
    b. The signature of the individual/parent/guardian indicating their consent for vaccine administration
    c. The name of the vaccine, dosage, manufacturer, lot number, site of injection, and date of expiration
    d. The signature of the health care provider administering the vaccine
    e. The date of the administration of the vaccine

9. The dosage of the influenza vaccine shall be determined by the following table:

Approved influenza vaccines for different age groups --- United States, 2009--10 season

Vaccine	Trade name	Manufacturer	Presentation	Mercury content (mcg Hg/0.5 mL dose)	Age group	No. of doses	Route
TIV*	Fluzone	Sanofi Pasteur	0.25mL prefilled syringe	0	6--35 mos	1 or 2[†]	Intramuscular[§]
			0.5 mL prefilled syringe	0	≥36 mos	1 or 2	Intramuscular
			0.5 mL vial	0	≥36 mos	1 or 2	Intramuscular
			5.0 mL multidose vial	25	≥6 mos	1 or 2	Intramuscular
TIV	Fluvirin	Novartis Vaccine	5.0 mL multidose vial	24.5	≥4 yrs	1 or 2	Intramuscular
TIV	Fluarix	GlaxoSmithKline	0.5 mL prefilled syringe	<1.0	≥18 yrs	1	Intramuscular
TIV	FluLaval	GlaxoSmithKline	5.0 mL multidose vial	25	≥18 yrs	1	Intramuscular
TIV	Afluria	CSL Biotherapies	0.5 mL prefilled syringe 5.0 mL multidose vial	0 25	≥18 yrs	1	Intramuscular
LAIV[¶]	FluMist**	MedImmune	0.2 mL sprayer	0	2--49 yrs	1 or 2[††]	Intranasal

* Trivalent inactivated vaccine. A 0.5-mL dose contains 15 mcg each of A/Brisbane/59/2007 (H1N1)-like, A/Brisbane/10/2007 (H3N2)-like, and B/Brisbane/60/2008-like antigens.

† Two doses administered at least 1 month apart are recommended for children aged 6 months--8 years who are receiving TIV for the first time and those who only received 1 dose in their first year of vaccination should receive 2 doses in the following year.

§ For adults and older children, the recommended site of vaccination is the deltoid muscle. The preferred site for infants and young children is the anterolateral aspect of the thigh.

¶ Live attenuated influenza vaccine. A 0.2-mL dose contains $10^{6.5-7.5}$ fluorescent focal units of live attenuated influenza virus reassortants of each of the three strains for the 2008--09 influenza season: A/Brisbane/59/2007(H1N1), A/Brisbane/10/2007(H3N2), and B/Brisbane/60/2008.

** FluMist is shipped refrigerated and stored in the refrigerator at 2°C--8°C (36°F to 46°F) after arrival in the immunization clinic. The dose is 0.2 mL divided equally between each nostril. FluMist should not be administered to persons with asthma. Health-care providers should consult the medical record, when available, to identify children aged 2--4 years with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving FluMist, parents or caregivers of children aged 2--4 years should be asked: "In the past 12 months, has a health-care provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months should not receive FluMist.

†† Two doses administered at least 4 weeks apart are recommended for children aged 2--8 years who are receiving LAIV for the first time, and those who only received 1 dose in their first year of vaccination should receive 2 doses in the following year.

The Advisory Committee on Immunization Practices (ACIP), 2009. MMWR, July 24, 2009;58:1-52.

10. If an adverse reaction should occur, the health care provider shall refer to "Medical Management of Vaccine Reactions in Children and Teens" (see attachment) available at http://www.immunize.org/catg.d/p3082a.pdf. An adult can be treated using the same protocol using the "13 years and older" dosing schedule.

11. A copy of the consent form shall be retained at the clinic site.

Dora Anne Mills, MD, MPH
Director, Maine Center for Disease Control and Prevention

9/14/09
Date

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. To minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions can occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

Reaction	Symptoms	Management
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

Supplies Needed

- ☐ Aqueous epinephrine 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen). If EpiPens are to be stocked, both EpiPen Jr. (0.15 mg) and adult EpiPens (0.30 mg) should be available.
- ☐ Diphenhydramine (Benadryl) injectable (50 mg/mL solution) and oral (12.5 mg/5 mL suspension) and 25 mg or 50 mg capsules or tablets
- ☐ Syringes: 1–3 cc, 22–25g, 1", 1½", and 2" needles for epinephrine and diphenhydramine (Benadryl)
- ☐ Pediatric & adult airways (small, medium, and large)
- ☐ Sphygmomanometer (child, adult & extra-large cuffs) and stethoscope
- ☐ Pediatric & adult size pocket masks with one-way valve
- ☐ Alcohol swabs
- ☐ Tongue depressors
- ☐ Flashlight with extra batteries (for examination of mouth and throat)
- ☐ Wrist watch
- ☐ Tourniquet
- ☐ Cell phone or access to an on-site phone

www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (8/06)

Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens

Signs and Symptoms of Anaphylactic Reaction

Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.

Treatment in Children and Teens

a. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

b. If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the on-call physician. This should be done by a second person, while the primary nurse assesses the airway, breathing, circulation, and level of consciousness of the patient.

c. Administer aqueous epinephrine 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.3 mg maximum single dose in children and 0.5 mg maximum in adolescents (see chart below).

d. In addition, for anaphylaxis, administer diphenhydramine either orally or by intramuscular injection; the standard dose is 1 mg/kg body weight, up to 30 mg maximum dose in children and 100 mg maximum dose in adolescents (see chart below).

e. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

f. If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 10–20 minutes for up to 3 doses, depending on patient's response.

g. Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

h. Notify the patient's primary care physician.

Suggested Dosing of Epinephrine and Diphenhydramine

Age Group Dose	**Weight * in kg**	**Weight (lbs)* in lbs**	**Epinephrine Dose** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tabs 50 mg/mL injectable
1–6 mos	4–7 kg	9–15 lbs	0.05 mg (0.05 ml)	5 mg
7–18 mos	7–11 kg	15–24 lbs	0.1 mg (0.1 ml)	10 mg
19–36 mos	11–14 kg	24–31 lbs	0.15 mg (0.15 ml)	15 mg
37–48 mos	14–17 kg	31–37 lbs	0.15 mg (0.15 ml)	20 mg
49–59 mos	17–19 kg	37–42 lbs	0.2 mg (0.2 ml)	
5–7 yrs	19–23 kg	42–51 lbs	0.2 mg (0.2 ml)	30 mg
8–10 yrs	23–35 kg	51–77 lbs	0.3 mg (0.3 ml)	
11–12 yrs	35–45 kg	77–99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50–100 mg

*Dosing by body weight is preferred.

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the _____ until rescinded or until _____.
name of clinic *date*

Medical Director's signature _____ Effective date _____

Sources: American Academy of Pediatrics. Passive Immunization. In: Pickering LK, ed. *Red Book: 2006 Report of the Committee on Infectious Diseases.* 27th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006: 64–66.
American Pharmacists Association, Grabenstein, JD, *Pharmacy-Based Immunization Delivery,* 2002.

www.immunize.org/catg.d/p3082a.pdf • Item #P3082a (8/06)